Docket No.: PF-0331-3 DIV

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By: / lene Kuns

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Bandma

Bandman et al.

Title:

NEW HUMAN CATHEPSIN

Serial No.:

To Be Assigned

Filing Date:

Herewith

Examiner:

To Be Assigned

Group Art Unit:

To Be Assigned

Mail Stop: Patent Application Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicants wish to call to the attention of the Examiner the enclosed "List of References Cited by Applicants." The right is reserved to antedate any item in accordance with standard procedure.

Applicants respectfully submit under 37 C.F.R. 1.98(3)(d) that copies of the references are not included herein as copies were previously cited by or submitted to the Office in parent application U.S. Application Serial No. 08/883,526 filed June 6, 1997, now U.S. Patent No. 6,033,893 and U.S. Application Serial No. 09/519,283, filed December 11, 2002, now U.S. Patent No. 6,620,606, which is a Continued Prosecution Application of U.S. Application Serial No. 09/519,283 filed March 2, 2000, from which we are claiming priority under 35 U.S.C. 120.

Citation of the documents is not to be construed as an admission that the documents are necessarily prior art with respect to the instant invention. This submission is understood to complement the results of the Examiner's own independent search. Citation of the documents shall not be construed as a representation that a search has been made or that the cited items are inclusive of all the relevant

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and material citations that may be available publicly. Any NCBI report included herein may not have an accurate date for prior art purposes. Some of the documents may have markings thereon. No significance is meant to be attached to the markings.

Applicants respectfully request that the cited documents be considered by the Examiner and that an initialed copy of the List of References Cited by Applicants be returned to Applicants.

It is believed that this disclosure complies with 37 CFR §§ 1.56, 1.97 and 1.98 and the Manual of Patent Examining Procedures § 609. If for some reason the Examiner considers otherwise, please telephone the undersigned.

Applicants believe that no fee is due with this paper. However, if the Commissioner determines that a fee is necessary, the Commissioner is hereby authorized to charge any additional fees associated with this communication or credit any overpayment to Deposit Account No. **09-0108.**

If there are any questions regarding the above, the Examiner is invited to call the undersigned.

Respectfully submitted,

INCYTE CORPORATION

Date: 12, September 2003

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LIST OF REFERENCES CITED BY APPLICANTS						Applicants			
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		Document	Date	Country	Class	Subclass	Yes	No	
		OTHER ART (Inc	luding Autho	r, Title, Date, P	ertinent	Pages, Etc	.)		
	1	Huisman, W. et al., "Role Of Individual Cathepsins In Lysosomal Protein Digestion As Tested By Specific Inhibitors", <u>Biochimica et Biophysica Acta</u> , 370: 297-307 (1974)							
	2	Mizuochi, T. et al., "Both cathepsin B and cathepsin D are necessary for processing of ovalbumin as well as for degradation of class II MHC invariant chain", Immunol. Lett. 43: 189-193 (1994)							
	3	Baldwin, E.T. et al., "Crystal structures of native and inhibited forms of human cathepsin D: Implications for lysosomal targeting and drug design", Proc. Natl. Acad. Sci. USA 90: 6796-6800 (1993)							
	4	Troen, B.R. et al., "Downstream Sequences Mediate Induction of the Mouse Cathepsin L Promoter by Phorbol Esters", Cell Growth Differ. 2: 23-31 (1991)						use (1991)	
	5	Keyszer, G.M. et al., "Comparative Analysis Of Cathepsin L, Cathepsin D, And Collagenase Messenger RNA Expression In Synovial Tissues Of Patients With Rheumatoid Arthritis And Osteoarthritis, By In Situ Hybridization", Arthritis Rheum. 38: 976-984 (1995)						D, And With	
	6	Baricos, W.H. et al., "Evidence Suggesting a Role for Cathepsin L in an Experimental Model of Glomerulonephritis", <u>Arch. Biochem. Biophys.</u> 288: 468-472 (1991)							
	7	Consonni, R. et al., "Further characterization of platelet-aggregating cysteine proteinase activity in thrombotic thrombocytopenic purpura", <u>Br. J. Hematol.</u> 87: 321-324 (1994)							
	8	Chambers, A.F. and A.B. Tuck, "Ras-Responsive Genes and Tumor Metastasis", Crit. Rev. Oncog., 4: 95-114 (1993)							
	9	Gal, S. et al., (Direct Submission) NCBI Accession No. X12451 (GI 29714, GI 29715) 22 Sep. 1998							
Examiner			Date Consi	dered					
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OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

OTHER	AKI	(Including Author, Title, Date, Pertinent Pages, Etc.)
	10	Gal, S. and M.M. Gottesman, "Isolation and sequence of a cDNA for human pro-(cathepsin L)", <u>Biochem. J.</u> 253: 303-306 (1988) (GI 29714; GI 29715)
	11	Okamura, N. et al., (Direct Submission) NCBI Accession No. D37917 (GI 710655, GI 1468964), 8 Feb. 1999
	12	Okamura, N. et al., "Direct evidence for the elevated synthesis and secretion of procathepsin L in the distal caput epididymis of boar", Biochimica et Biophysica Acta 1245: 221-226 (1995) (GI 710655; GI 1468964)
	13	Adams et al., "Initial Assessment of Human Gene Diversity and Expression Patterns Based Upon 83 Million Nucleotides of cDNA Sequence", Nature 377(6547 Supp.): 3-17 (1995)
	14	Adams et al., "EST177928 Colon carcinoma (HCC) cell line Homo sapiens cDNA 5' end similar to cathepsin L", EST Accession No. AA307011 (April 18, 1997)
	15	Hillier et al., "zs40d02.s1 Soares NhHMPu S1 Homo Sapiens cDNA clone 687651 3' similar to gb:X12451 cathepsin L precursor (human)", EST Accession No. AA235364 (March 3, 1997)
	16	Gay et al., "Molecular Cloning of a Bovine Cathepsin", <u>Biochem. J.</u> 225: 707-712 (1985)
	17	Georgiou, "Optimizing the Production of Recombinant Proteins in Microorganisms", AlChE. J. 34(8): 1233-1248 (1988)
Ÿ	1,8	Hillier, L. et al., (Direct Submission) NCBI Accession No. AA478227 (GI 2206861), 20 Dec. 1996
	19	Linnevers, C. et al., "Human cathepsin W, a putative cysteine protease predominantly expressed in CD8+ T-lymphocytes", <u>FEBS Letters</u> 405: 253-259 (1997)
	20	Santamaria, I et al., "Cathepsin L2, a Novel Human Cysteine Proteinase Produced by Breast and Colorectal Carcinomas", <u>Cancer Research</u> 58: 1624-1630 (1998)
	21	Bromme, D. et al., (Direct Submission) NCBI Accession No. AF070448 (GI 3228671), 17 June 1998
	22	Adachi, W. et al., (Direct Submission) NCBI Accession No. AB001928 (GI 3107914), 5 May 1998
	23	Okubo, K., (Direct Submission) NCBI Accession No. BAA25909 (GI 3107915), 13 Feb. 1999
	24	Okubo, K., (Direct Submission) NCBI Accession No. AB001928 (GI3107914), 13 Feb. 1999
	25	Adachi, W. et al., "Isolation and Characterization of Human Cathepsin V: A Major Proteinase in Corneal Epithelium", <u>Invest. Ophthalmol. Visual Sci.</u> , 39: 1789-1796 (1998)
	26	E. K. Lobenhofer, et al., <u>Environmental Health Perspectives</u> 109:881-891 (2001)
Examiner		Date Considered

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Serial No.:

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

	·	OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.
	27	John C. Rockett, et. al., Xenobiotica 29:655-691 (July 1999)
	28	Emile F. Nuwaysir, et al., Molecular Carcinogenesis 24:153-159 (1999)
	29	Sandra Steiner & N. Leigh Anderson, <u>Toxicology Letters</u> 112-13:467-471 (2000)
	30	John C. Rockett & David J. Dix, 107 Environ. Health Perspec. 681, No. 8 (1999)
	31	E-mail from Dr. Cynthia Afshari to an Incyte employee, dated July 3, 2000
	32	C.A. Afshari, et al., <u>Cancer Research</u> 59:4759-4760 (1999)
	33	P.A. Clarke, et al., Biochemical Pharmacology 62:1311-1336 (2001)
	34	R.P. Amin, et al., <u>Toxicology</u> 181-182:555-563 (2002)
	35	J.F. Waring and R.G. Ulrich, Ann. Rev. Pharm. Tox. (2000)
	36	Lashkari et al., <u>Proc. Nat. Acad. Sci.</u> 94:8945-8947 (1997)
	37	Brenner et. al., <u>Proc. Natl. Acad. Sci.</u> 95:6073-78 (1998)
	38.	Brömme, D. et al., "Human Cathepsin V Functional Expression, Tissue Distribution, Electostatic Surface Potential, Enzymatic Characterization, and Chromosomal Localization," <u>Biochem.</u> 38:2377-2385 (1999)
	39	Bühling, F. et al., Review chapter (2000) "Cellular Peptidases in Immune Functions and Diseases 2," Langner and Ansorge, editors, Kluwer Academic/Plenum Publishers, pp. 241-254
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Examiner		Date Considered

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